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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PAUL HABERMANN and RUDOLF BENDER

Appeal 2008-1720[1]
Application 09/664,326
Technology Center 1600

Decided: June 25, 2008

Before TONI R. SCHEINER, DEMETRA J. MILLS, and
MELANIE L. McCOLLUM, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a detection method. The Examiner has rejected the claims as lacking written description. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

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[1] Heard June 12, 2008.

STATEMENT OF THE CASE

Claims 6-9 are pending and on appeal. We will focus on claim 6, the broadest claim on appeal, which reads as follows:

> 6. A process for selecting a signal peptide for secretory expression of a desired hirudin or hirudin derivative protein in E. coli, comprising:
>
> (a) expressing in *E. coli* in culture medium, hirudin or a hirudin derivative which has antithrombotic activity, and which has a defined amino acid, aa_x, at its N terminus, wherein said amino acid is connected via its N-terminal to a test signal peptide;
>
> (b) determining expression rate by measuring said hirudin or hirudin derivative activity in the culture supernatant;
>
> (c) repeating steps (a) and (b) with various signal peptides;
>
> (d) selecting said signal peptide by comparing the expression rates represented by the hirudin or hirudin derivative antithrombotic activity found in step (b)
>
> wherein the E. coli bacteria are not E. coli secretor mutants.

Claims 6-9 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. In particular, the Examiner finds that the "claim limitation that 'the *E. coli* bacteria are not *E. coli* secretor mutants' . . . is considered new matter" (Ans. 3).

Appellants contend that they "were in possession of a process 'wherein the E. coli bacteria are not E. coli secretor mutants' at the time of filing" (App. Br. 10 (emphasis deleted)). In particular, Appellants argue that the Specification "clearly convey[s] to one of ordinary skill in the art that Applicants were in possession of methods wherein *E. coli* bacteria in general were used, regardless of whether the *E. coli* bacteria were, or were not, secretor mutants" (*id.* at 12). In addition, the Specification states that

"[c]ompetent cells of the *E. coli* strain Mc1061, or the secretor mutant WCM100, were transformed with the ligation mixture and grown under selection pressure on ampicillin-containing plates" (*id.* at 10 (quoting Spec. 9)). Appellants argue that, upon reading this passage, "one of ordinary skill in the art would clearly understand that secretor mutants can be used in the methods of the invention, and, therefore, that Applicants were in possession of such methods. Therefore, Applicants can properly exclude such subject matter from the claims." (App. Br. 14.)

ISSUE

The issue is whether amending claim 6 to exclude *E. coli* secretor mutants introduced new matter into this claim.

FINDINGS OF FACT

1. The Specification states that an "aspect of the invention is a process for finding a suitable signal peptide for secretory expression of any desired protein in *E. coli*" (Spec. 5:21-22).

2. The Specification states that, in the process, "hirudin or a hirudin derivative . . . which is connected N-terminally to a signal peptide to be tested is expressed in *E. coli*" (*id.* at 5:23-25).

3. These descriptions generally refer to *E. coli* and do not specify secretor mutants or non-secretor mutants (Spec. 5-6).

4. As originally filed, claim 6 was directed to a "process for selecting a suitable signal peptide for secretory expression of a desired protein in *E. coli*, comprising: (a) expressing in *E. coli* in culture medium, hirudin or a hirudin derivative. . . ." (*id.* at 21).

5. As originally filed, claim 6 generally referred to *E. coli* and did not specify secretor mutants or non-secretor mutants (*id.*).

6. In the May 30, 2006, Final Rejection, the Examiner states that "the Specification as a whole teaches that any E. coli strain could be used and [that the particular strain] is not important to the invention" (Final Rejection 4).

7. In Example 1, the Specification describes synthesizing "a fusion gene coding for a fusion protein consisting of Leu-hirudin and [a] signal sequence" (Spec. 7:9-10).

8. The Specification states that the reaction product was inserted into vector DNA, which was opened in a ligase reaction (*id.* at 8:27-29).

9. In addition, the Specification states:

> Competent-cells of the *E. coli* strain Mc1061, or the secretor mutant WCM100, were transformed with the ligation mixture and grown under selection pressure on ampicillin-containing plates. The next morning, expression . . . was then compared with Ala-hirudin expression using the *E. coli* strain WCM100/pCM7053. It was found that the expression obtained was about 1.5 times better than in the comparative test.

(*Id.* at 9:1-6.)

ANALYSIS

Compliance with the written description requirement is determined by whether the disclosure shows possession to a person of skill in the art. *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000). In *In re Johnson*, 558 F.2d 1008 (CCPA 1977), claims originally directed to a chemical genus were amended to exclude two

disclosed species within the genus. In reversing the rejection for failure of the specification to describe the claimed subgenus, the Court stated:

> The notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of § 112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute.

In re Johnson, 558 F.2d at 1019.

The Specification refers to a process for finding a suitable signal peptide for secretory expression of a protein in *E. coli* comprising expressing a protein in *E. coli* (Findings of Fact (FF) 1-5). The Examiner does not allege that Appellants' Specification fails to provide written description for processes that utilize *E. coli* generally. In fact, the Examiner states that "the Specification as a whole teaches that any E. coli strain could be used and [that the particular strain] is not important to the invention" (FF 6).

In addition, the Specification clearly indicates that Appellants were in possession of utilizing the *E. coli* strain WCM100 to express a fusion gene coding for a fusion protein consisting of Leu-hirudin and a signal sequence (FF 7-9). The Specification also identifies *E. coli* strain WCM100 as a secretor mutant (FF 9). We agree with Appellants that this teaching, together with the teaching of using *E. coli* generally (FF 1-6), demonstrates that Appellants were in possession of a process using *E. coli* secretor mutants as the *E. coli* bacteria. Therefore, as in *In re Johnson* discussed above, we agree with Appellants that the Examiner's finding that excluding

E. coli secretor mutants introduces new matter results from "a hypertechnical application" of 35 U.S.C. § 112, first paragraph.

The Examiner argues, however, that *E. coli* strain Mc1061 is "not identified [in the Specification] as an *E. coli* strain that [is] not a secretor strain and there is nothing in the Specification to suggest that it is" (Ans. 4). However, the issue raised in this appeal is whether Appellants have described *E. coli* secretor mutants with sufficient particularity to exclude them, not whether Appellants have described non-secretor mutants.

The Examiner also argues:

> In the example that mentions *E. coli* Mc1061, the Specification does not indicate which *E. coli* strain (Mc1061 or WCM100) was used in the tests and which gave the expression that was 1.5 times better than the comparative test (Ala-hirudin expression using WCM100/pCM7053). . . . Therefore, the Specification does not suggest using a non-secretor strain of *E. coli* and there would be no obvious reason to do so, especially given that the claim requires secretory expression.

(*Id.*) Assuming this example does not indicate whether transformation of the product in *E. coli* strain Mc1061 or *E. coli* secretor mutant WCM100 or both provides 1.5 times better expression than in the comparative test, we do not agree that this demonstrates that the exclusion of secretor mutants constitutes new matter. Applicants are entitled to claim less advantageous embodiments that have been described in their specification and are otherwise patentable. As stated in *In re Johnson*, "[i]t is for the inventor to decide what *bounds* of protection he will seek." 558 F.2d at 1018. Thus, the failure to indicate that non-secretor mutants are advantageous has no bearing on whether they have been described.

> In addition, the Examiner argues that
>
> unlike *In re Johnson* where the excluded species were equivalent to the species allowed in the claims, in the present case which is drawn to a method of expression that requires secretion, it is unclear that non-secretor mutants and secretor mutants would function equivalently. The Specification and the art do not provide any guidance or evidence that non-secretor strains would work as well as secretor mutants in the present invention. In fact, it is likely that non-secretor mutants could not be used successfully in the claimed method because only a limited and unmeasurable amount of protein could be secreted. Thus, one of skill in the art would not readily recognize that Appellants were in possession of the claimed invention at the time of filing.

(Ans. 7-8.) However, we do not agree that the excluded species need to function equivalently to the non-excluded species. As discussed above, Appellants are entitled to claim less advantageous embodiments that have been described in their specification and are otherwise patentable.

> The Examiner also argues that
>
> unlike *In re Johnson*, the present case does not teach how to make and use *numerous species* within the genus. . . . . Thus, it would not be apparent to the skilled artisan, in reading the present Specification, that such a method limited to using only non-secretor *E. coli* strains was contemplated at the time of filing the Application.

(Ans. 9.) However, as discussed above, the issue raised in this appeal is whether Appellants have described *E. coli* secretor mutants with sufficient particularity to exclude them, not whether Appellants have described non-secretor mutants. In addition, *In re Johnson* does not require that it be apparent from the Specification that only the embodiments that have not been excluded were contemplated at the time the Application was filed. As

in the present case, the Specification at issue in *In re Johnson* described a genus that included the excluded embodiments. 558 F.2d at 1011-1012.

CONCLUSION

The Examiner has not shown that the claims lack written description. We therefore reverse the rejection of claims 6-9 under 35 U.S.C. § 112, first paragraph.

REVERSED

clj

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